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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,484	01/23/2002	Keith Alan Foster	1581.0870000/RWE/MTT	2134

7590 01/29/2004

Sterne Kessler Goldstein & Fox
Suite 600
1100 New York Avenue NW
Washington, DC 20005-3934

EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,484	FOSTER ET AL.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *30-47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Information Disclosure Statement

Although the application has not yet been examined on the merits, it is noted that the information disclosure statements filed on 1/23/02 and 4/13/02 fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; *each publication* or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Namely, no publications were found in the file. It is suggested that Applicant include copies of these references in the response to this action.

Response to Original Election/Restrictions and Amendment

Applicant's election with traverse of Groups II, claims 39-42 and 47 in the Office Action of October 3, 2003 is acknowledged. Additionally, Applicant's amendment of claim 39 is acknowledged. The traversal is on the ground(s) that the Examiner did not properly restrict the claims under 37 C.F.R. § 1.475(b)(2), the Administrative Instructions Under the PCT, Annex B, Part 1 (emphasis added) and Examples therein, that the no art is cited to support the allegation of lack of unity of invention, and that it is improper to require restriction of single claims (35 U.S.C. § 121).

The original restriction was as follows:

I. Claims 30-38, and 45-46 are drawn to a conjugate or nucleic acid containing the conjugate, classified in class 530, subclass 300+.

II. Claims 39-42, and 47 are drawn to a method of using the composition, classified in

class 514, subclass 2.

III. Claims 43-44 are drawn to a method of preparing a compound, classified in class 424, subclass 1.69.

Based on the amendment of the claims, further review of the subject matter of the claims, and Applicant's grounds of traversal (particularly that no art was cited in support to show that the special technical feature linking all claims was known), the following supplemental restriction is being sent to further clarify the different inventions and lack of unity of the claimed subject matter.

As to Applicant's traversal of the restriction requirement under 35 U.S.C. § 121 (notwithstanding other grounds of traversal which are not herein addressed), it is clarified at the outset, that restriction of a single claim, even under 35 U.S.C. § 121 is not improper, particularly if the special technical feature is not novel, as discussed below. Were the alternative true, an Applicant could include an innumerable number of inventions, which not even be related, in a single claim of application and expect examination of the merits of each.

Supplemental Election/Restrictions

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 30-37, drawn to a conjugate of lectin (non-endogenous to humans) and a peptide/protein (substantially free of Clostridial neurotoxin enzyme activity), classified in class 530, subclass 300+.

II. Claim 38 drawn to a nucleic acid sequence encoding a conjugate of lectin (non-endogenous to humans) and a peptide/protein (substantially free of Clostridial neurotoxin enzyme activity), classified in class 435, subclass 5+.

III. Claims 39-42, drawn to a method of treating a disease or condition comprising administering an effective amount of a lectin, classified in class 514, subclass 2.

IV. Claims 39-42, drawn to a method of treating a disease or condition comprising administering an effective amount of a nucleic acid sequence coding a lectin, classified in class 514, subclass 2.

V. Claims 39-42, drawn to a method of treating a disease or condition comprising administering an effective amount of conjugate of lectin (non-endogenous to humans) and a peptide/protein (substantially free of Clostridial neurotoxin enzyme activity), classified in class 514, subclass 2.

VI. Claims 39-42, drawn to a method of treating a disease or condition comprising administering an effective amount of a nucleic acid sequence encoding a conjugate of lectin (non-endogenous to humans) and a peptide/protein (substantially free of Clostridial neurotoxin enzyme activity), classified in class 514, subclass 2.

VII. Claims 43-44, drawn to a method of preparing a conjugate of lectin (non-endogenous to humans) and a peptide/protein (substantially free of Clostridial neurotoxin enzyme activity) comprising coupling the compounds together, classified in class 424, subclass 1.69+.

VIII. Claims 43-44, drawn to a method of preparing a conjugate of lectin (non-

endogenous to humans) and a peptide/protein (substantially free of Clostridial neurotoxin enzyme activity) comprising expressing in a host cell a nucleic acid sequence capable of encoding said conjugate, classified in class 424, subclass 1.69+.

IX. Claims 45-46, drawn to a lectin AND a peptide or protein (AS OPPOSED TO A CONJUGATE of the two compounds), classified in class 530, subclass 300+.

X. Claims 47, drawn to a method of treating a disease or condition comprising administering a lectin AND a peptide or protein (AS OPPOSED TO A CONJUGATE of the two compounds), classified in class 514, subclass 2.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) a product and a process specially adapted for the

manufacture of said product; or (2) a product and a process of use of said product; or (3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) a process and an apparatus or means specifically designed for carrying out the said process; or (5) a product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).

After a closer review of the subject matter of the claims, the only discernable alleged special technical feature *that is part of every claimed invention (Groups I-X) is a lectin* (i.e. Group III, claims 39-42, drawn to a method of treating using *only a lectin*). However, if a lectin is the special technical feature, *a lectin alone does not run through every invention claimed* (i.e. for instance, claim 30 is drawn to a lectin-peptide/protein conjugate and claim 38 is drawn to a nucleic acid that encodes a conjugate, not a lectin alone). Thus, there is no special technical feature among Groups I-X and they lack unity.

However, even if lectin is argued as a special technical feature, lectin (even from Erythrina cristagalli) is a known compound used in the treatment of disease (i.e. Applicant's claim 39, Group III). Mathiowitz (US 6235313 B1) teach the use of a lectin from Erythrina cristagalli in a composition with a peptide for treatment of such diseases or conditions as inflammation (abstract; col. 10, lines 60 and 67 to col. 11, line 1; claim 2). Thus, even if a lectin could be argued as the special technical feature among the inventions, lectins are known even in

treating diseases such as inflammation, and are not novel. Therefore, the inventions of Group I-X would also lack unity under this prong.

Additionally, the inventions are distinct, each from the other because of the following reasons:

Inventions I, II, and IX are drawn to different conjugates, nucleic acids, or compositions, that may not be searched coextensively and require separate structure and/or sequences searches.

Inventions I, II, and IX and III-VI and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method may be practiced by any number of undisclosed lectin, peptides, nucleic acids, compositions, or conjugates (as the claims are indefinite as to which ones may be used or may not be used).

Inventions I, II, and IX and VII and VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the conjugates (Group I), nucleic acids (Group II), and compositions (Group IX) may be made by other synthetic processes, for instance by individual residue synthesis rather than coupling together.

The methods of treating in Groups III-VI and X are directed to different inventions, which are not connected in design, operation, and/or effect. These methods are independent since they are not disclosed as capable of use together, they have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone.

The methods of making in Groups VII and VIII are directed to different inventions, which are not connected in design, operation, and/or effect. These methods are independent since they are not disclosed as capable of use together, they have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone.

ELECTION OF A COMPOUND/COMPOSITION OF THE INVENTION

The inventions do not contain a distinguishable structure (i.e. lectin, peptide, protein, nucleic acid, conjugate, or composition) that may be searched. Therefore, as part of electing one of Groups I-X, Applicant is required to elect a specific lectin, peptide, protein, nucleic acid, conjugate, or composition (depending on the Group elected and the compound structure therein), and submit a structure to that that compound, to which the elected invention will be examined on the merits as drawn to**, and** so that a search of the invention may be undertaken. **[It is also suggested that the claims be amended to include this compound either by structure or chemical nomenclature]. This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each compound/composition is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.**

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference, which would anticipate the invention of one group, would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Restriction for examination purposes is therefore proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CRF 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 703-305-5039. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-1234 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

MA
January 25, 2004

HERBERT J. LILLING
PATENT EXAMINER
GROUP 1600 ART UNIT 1651